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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,414	04/07/2005	Kenji Miyamoto	12218/39	6892
23838 7590 04/09/2007 KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER LILLING, HERBERT J	
			ART UNIT	PAPER NUMBER
			1657	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/507,414

Applicant(s)

MIYAMOTO ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-13-04; 3-24-05 & 7-14-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3-24-05 & 7-14-05</u> | 6) <input type="checkbox"/> Other: _____ |

1. Receipt is acknowledged of a preliminary amendment to the claims and specification, drawing and certified copy of foreign priority filed September 13, 2004 and prior art information disclosure statements filed March 24, 2005 and July 14, 2005.

2. Claims 1-9 are present in this application, which is a 371 national phase application of PCT/JP03/05323 filed on 25 April 2002, claiming priority to JP 2002-125881, filed on 26 April 2002.

3. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention the claimed "cells of ... the poly-3-hydroxyalkanoic acid-containing microbial cells are cells of a strain of microorganism transformed by a poly-3-hydroxyalkanoic acid synthase group gene derived from Aeromonas caviae."

The specification lacks the sufficient enabling disclosure as well as any indication of a deposit of the specific strain derived from *Aeromonas caviae*.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Choi et al.; Harrison et al.

Choi et al teaches on pages 548-549, see in particular Table I whereby the digestion with various alkaline additives were acted on recombinant microorganisms to obtain poly –3- hydroxybutyric acids have varying molecular weights at 30 deg C and 37 deg C.

Harrison et al., teaches on page 97, treatment of strain at a temperature of 23 deg C with KOH from 8.5 to 10 for the mechanical and chemical cell disruption for the recovery of PHB, see page 97-98.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al or Harrison et al as noted above further in view of Huisman, Gjalt W., et al. U.S. application 20040014197 [03-30-1998], effective filing date is APPL-NO: 10/607903 DATE FILED: June 27, 2003 which Application 10/607903 is a continuation-of US application 09/456940, filed December 7, 1999, which Application 09/456940 is a division-of US application 09/281363, filed March 30, 1999, ABANDONED which Application is a non-provisional-of-provisional application 60/079938, filed March 30, 1998,

It would have been prima facie obvious to use *Aeromonas caviae* [claim 8] or modify [claim 9] the strain(s) of Huisman, Gjalt W., et al. or Yokomizo et al., U.S. 7,083,972 [18 May 01] for strain or transformant for producing PHA polyester for the polyesters disclosed by Yokomizo et al:

“A PHA (polyhydroxyalkanoic acid)-synthase gene was cloned from a P (3HB-co-3HH)-producible strain of *Aeromonas caviae* [T. Fukui, Y. Doi: J. Bacteriol, Vol. 179, No. 15, 4821-4830 (1997), Japanese Kokai Publication Hei-10-108682]. When this gene was introduced into *Ralstonia eutropha* (formerly, *Alcaligenes eutrophus*) and the production of P (3HB-co-3HH) was carried out using the resulting transformant, the cell output was 4 g/L and the polymer content was 30%. Further, by growing this transformant on vegetable oil as the carbon source, a cell content of 4 g/L with a polymer content of 80% could be accomplished [T. Fukui et al.: Appl. Microbiol. Biotechnol. 49, 333 (1998)].”;

for the strain of Choi et al or Harrison et al in view of the disclosure which Choi et al recites:

“ nuclease gene is integrated into a host strain selected from the group consisting of *Ralstonia eutropha*, *Methylobacterium organophilum*, *Methylobacterium extorquens*, *Aeromonas caviae*, *Azotobacter vinelandii*, *Alcaligenes latus*, *Pseudomonas oleovorans*, *Pseudomonas fluorescens*, *Pseudomonas putida*, *Pseudomonas aeruginosa*, *Pseudomonas acidophila*, *Pseudomonas resinovorans*, *Escherichia coli*, and *Klebsiella*” ;

to obtain the advantages as disclosed to obtain greater recovery for the polymers as recited by Harrison et al:

Art Unit: 1657

" These strains secrete nuclease into the periplasm or growth medium in an amount effective to enhance productivity and/or recovery of polymer, and are particularly suited for use in high cell density fermentation processes."

6. **No claim is allowed.**

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1657**
April 01, 2007



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657